PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	Bicek et al.	Examiner:	Nguyen, V.X.
Serial No.:	09/974,653	Group Art Unit:	3734
Confirmation No.:	9912	Docket:	760-49 RCE
Filed:	October 10, 2001	Dated:	April 16, 2007
For:	STENT DESIGN WITH SHEATH ATTACHMENT MEMBERS		

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on **April 16, 2007**.
Signed: Mary Fawsehon

APPEAL BRIEF

Sir:

Appellants have appealed the Examiner's Final Rejection of Claims 17 to 20, 22 to 24, and 39 to 55 dated September 13, 2006. This Brief is submitted in accordance with the provisions of 37 C.F.R. §41.37. As required by 37 C.F.R. §41.37(a)(2), please charge Deposit Account No. 08-2461 the requisite fee of $500.00 for submitting a Brief in support of an appeal. If additional fees are required, please charge Deposit Account No. 08-2461.

I. Real Party In Interest

The subject application is owned by SCIMED Life Systems, Inc., which is a wholly-owned subsidiary of Boston Scientific Corporation.

II. Related Appeals and Interferences

There are no known related appeals or interferences.

III. Status of Claims

Claims 17 to 20, 22 to 27 and 39 to 55 are in the application.

Claims 1 to 16, 21 and 28 to 38 have been cancelled.

Claims 25 to 27 are presently withdrawn from consideration.

Claims 17 to 20, 22 to 24 and 39 to 55 are finally rejected and on appeal.

No claims presently stand allowed.

IV. Status of Amendments

On November 13, 2006, a Response to Final Office Action of September 13, 2006 was filed which did not amend any claims, but argued for patentability of the claims. In effect, the Response was a request for reconsideration. In an Advisory Action dated January 16, 2007, the Examiner indicated his disagreement with the position forwarded by the Response.

V. Summary of Claimed Subject Matter

The subject invention is directed to a covered stent including a main stent and at least a support stent having a sheath interposed therebetween (Page 12, Lines 15 to 17). The subject invention and its method allows practitioners to selectively choose a sheath as a covering for a stent at a point-of-use, prior to implantation (Page 3, Lines 9 to 12). With this versatility, a practitioner has the ability to utilize not only polymeric sheaths, *inter alia*, but also enhance the stent by plastically-deforming the support stent (Page 3, Lines 21 to 26).

The subject invention includes particular features such as, no portions of the main stent being in contact with any portion of the support stent (Page 9, Line 6 and 7). Additionally, the main stent and the support stent together generate a relative pressing force solely acting to hold the sheath in place (Page 9, Lines 13 to 14). Furthermore, the sheath is not bonded to either the support stent or the main stent (Page 9, Lines 1 to 2).

Map to the Reference for Independent Claim 17:

The "main stent **10** having a radially-expandable body" is disclosed on page 9, line 3 (¶ [0033]);

the "at least one support stent **30** having an axial length less than the axial length of said body" is disclosed on page 9, lines 1-2 (¶ [0033]); and

the "sheath **28** interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent" is disclosed on page 9, line 2 (¶[0033]).

Map to the Reference for Independent Claim 40:

The "main stent **10** having a radially-expandable body" is disclosed on page 9, line 3 (¶ [0033]);

the "at least one support stent **30**" is disclosed on page 9, lines 1-2 (¶ [0033]); and

the "sheath **28** interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent" is disclosed on page 9, line 2 (¶[0033]).

Map to the Reference for Independent Claim 48:

The "main stent **10** having a radially-expandable body" is disclosed on page 9, line 3 (¶ [0033]);

the "at least one support stent **30**" is disclosed on page 9, lines 1-2 (¶ [0033]); and

the "polymeric sheath **28** interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent" is disclosed on page 9, line 2 (¶[0033]).

Specifically, with reference to Figure 5, a stent 10 (hidden from view, but similar to the stent 10 discussed in paragraphs 21 and 22) having a radially expandable body is shown as a stent example of a covered stent of claims 17, 40, and 48 which may be used in the invention. The body of stent 10 defines a tubular body having a first axial end and a second axial end.

The Figure 5 also shows a pair of ring-shaped support stents 30 to provide holding force for the sheath 28.

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

A. Whether claims 17 to 20, 22 to 24 and 39 to 55 are unpatentable under 35 U.S.C. §102(b) over U.S. Pat. No. 5,916,264 to Von Oepen et al. (the "Von Oepen et al. '264" reference, hereinafter).

B. Whether claims 17, 39 to 40 and 48 are unpatentable under 35 U.S.C. §102(b) over U.S. Pat. No. 5,865,723 to Love (the "Love '723" reference, hereinafter).

VII. Argument

A. 102(b) Rejection of Claims 17 to 20, 22 to 24 and 39 to 55 Over the Von Oepen et al. '264 Reference

1. The Von Oepen et al. '264 Reference Does Not Disclose Each & Every Claimed Feature

Claims 17 to 20, 22 to 24, and 39 to 55 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by the Von Oepen et al. '264 reference. This is based on the Examiner's position that the Von Oepen et al. '264 reference discloses each and every limitation of the claims 17 to 20, 22 to 24, and 39 to 55. A claim is anticipated if each and every limitation of claim is found either expressly or inherently in a single prior art reference. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984). It is respectfully submitted that the Von Oepen et al. '264 reference does not disclose each and every feature of the claims, and thus, this rejection is improper.

2. The Von Oepen et al. '264 Reference Requires the Ends of Both Stents to be Connected to Each Other

The Von Oepen et al. '264 reference discloses two coaxially arranged stents **11** and **12**, and a flexible, stretchable material layer **13** arranged between the stents. As indicated in the abstract of the reference, the Von Oepen et al. '264 reference discloses that "*both stents are directly connected with one another in their end regions.*" As stated in column 1, lines 45 to 47 of the Von Oepen et al. '264 reference, the end connections are required because: *"both stents are connected with one another punctually in their end regions to prevent an opposite side displacement of both stents during reinsertion."* In other words, if the stents are not connected with one another, one of the stents may slip in relation to the other during insertion. This is further substantiated throughout the specification of the Von Oepen et al. '624 reference. (See, col. 1, lines 45-50; col. 2, lines 27-29; col. 2, lines 52-54). Moreover, claim 1 of the Von Oepen et al. '264 reference states "*both said stents being directly connected with one another in their end regions*". (Col. 2, lines 53-54). Thus, the device according to Von Oepen et al. '624 reference, requires the ends of the stents to be directly connected to each other.

3. The Sole Drawing Does Not Disclose a Shorter Outer Stent Out of Contact from a Longer Inner Stent

One may be initially misled into believing that the sole drawing of the Von Oepen et al. '264 reference shows the length of the outer stent **12** as being shorter and limited, and therefore, not directly touching the inner stent **11**. However, according to the Brief Description of the Drawings, the single figured drawing shows "*a partially sectioned perspective view of a stent graft*" and does not show the full product. (Col. 2, lines 11-13). As discussed above, the stent **12** and the stent **11** are described throughout the Von Oepen et al. '264 reference as being directly connected to each other at the ends to avoid being displaced. The drawing adds nothing further to the written description of the Von Oepen et al. '264 reference and is consistent therewith.

4. <u>The Material Layer 13 Overlaps Only a Part of the Stent</u>

The Von Oepen et al. '264 reference also specifically discloses that the material layer **13** partially overlaps the stents **11** and **12**, thus leaving the stents **11** and **12** in direct contact with each other. In particular, reference is made to column 2, lines 25 to 29, wherein it states:

> "*The material layer **13** overlaps only one part of the stents **11, 12**. The both stents **11, 12** can be connected with one another in their end regions punctually, by a plurality of points.*"

With the material layer **13** only partially overlapping the stents **11, 12**, it is clear that the non-overlapped parts of the stents **11, 12** are in contact in their end regions.

5. <u>No Portion of the Main Stent According to the Present Invention Directly Contacts the Support Stent</u>

All independent claims 17, 40 and 48 of the subject application, are each directed to a covered stent including *"a main stent having a radially-expandable body"* and *"at least one support stent"* with a sheath *"interposed between said body and said at least one support stent."* Further, each of the independent claims states that *"no portions of said main stent being in contact with said at least one support stent."* In contrast, the stents **11, 12** of the Von Oepen et al. '624 reference are only partially overlapped by the material layer **13** and, as such, are in contact at their end regions. The stents **11, 12** are only disclosed as being connected at their end regions. There is no disclosure or suggestion in the Von Oepen et al. '264 reference to provide the material layer **13** along the full length of the device or to avoid end connections between the stents **11, 12**.

It is respectfully submitted that the Von Oepen et al. '264 reference does not disclose each and every feature present in the claims and, as such, it does not anticipate the present invention as claimed.

In addition, dependent claims 18 to 20, 22 to 24, 39, 41 to 47, and 49 to 55 depend from independent claims 17, 40, and 48 and incorporate all of the combination of features thereof. The patentability of the dependent claims is, therefore, based upon the patentability of the independent claims. In view of the foregoing, it is respectfully submitted that claims 17, 40 and

48, along with dependent claims 18-20, 22-24, 39, 41-47 and 49-55, are patentable over the Von Oepen et al. '264 reference.

B. The 102(b) Rejection of Claims 17, 39, 40 and 48 Over the Love '723 Reference

In the Final Office Action dated September 13, 2006, the Examiner rejected claims 17, 39, 40 and 48 as being anticipated by the Love '723 reference. The Love '723 reference discloses several embodiments of a vascular prosthesis and the Examiner relied, in particular, on the stent graft shown by Figures 1 and 2. However, it is Applicants' position that the Love' 723 reference fails to anticipate or suggest the present invention as claimed.

1. Claims 17 and 39

Claim 17 is an independent claim and claim 39 depends therefrom. Claim 17 is directed to a covered stent which includes, *inter alia*, "a main stent" and "at least one support stent having an axial length less than the axial length of said body" of the main stent. The Love '723 reference discloses features which do not anticipate the present invention as claimed. The stent graft relied on by the Examiner is described in the Love '723 reference as follows:

> *In a first embodiment, the tubular support frame includes at least an inner frame component and an outer frame component, where the attaching step comprises capturing the tissue sheet between the inner component and the outer frame component. The inner and outer frame components may be in the form of helices, longitudinally spaced-apart rings, or other conventional intravascular stent structures and the like. In a preferred*

> *aspect of the present invention, the inner and outer frame components comprise concentric mating structure which clamp the tissue therebetween without suturing. The frame thus supports the clamped tissue* ***along the entire length of the graft*** *to provide support and precise dimensional control.*

(Column 3, Lines 37 to 50) (Emphasis added).

According to the Love '723 reference, the frame supports the clamped tissue along the entire length of the graft (column 3, lines 48 to 50) to prop up its structure. This is especially required since the clamped tissues have unbound and loose rolled edges wherein "*the rolled edges are overlapped by an arc of at least 35° usually being in the range from 45° to 135°, preferably being about 120°*". (Column 7, lines 6 to 9). Thus, the Love '723 reference offsets the unfixed mobile nature of the clamped tissue with an inner frame and an outer frame which run along the entire length of the graft to prevent blockage and allow patency during and after insertion.

The inner frame and the outer frame having the same length is further substantiated in numerous places in the Love '723 reference disclosure. Specifically, column 6, lines 35 to 37 states that "*the dimensions of the tubular support frame will define the dimensions of the vascular prostheses.*" Additionally, column 7, lines 48 to 49 states, *"[t]he helical support elements **14** and **16*** [i.e., the inner and the outer support frames] *will usually have identical dimensions, i.e., diameter, length, and pitch.*" With identical dimensions, the support elements **14** and **16** will have the same length.

In contrast, the present invention as claimed in claim 17 provides for "*at least one support stent having an axial length less than the axial length of said body.*" The Love '723 reference does not disclose having one of the support elements **14, 16** be shorter than the other. Thus, the present invention as claimed in claim 17 clearly is not anticipated by the Love '723 reference. With the subject invention, a practitioner can utilize an axially shorter support stent with a main stent to assemble a prosthesis device at point-of-use.

In addition, dependent claim 39 depends from independent claim 17 and incorporates all of the limitations thereof. The patentability of claim 39 is, therefore, based upon the patentability of claim 17 and for the reasons set forth above, claim 17 is patentably distinct over Love '723 reference. In view of the foregoing, it is respectfully submitted that claim 39 is also patentable over the Love '723 reference.

2. Claim 40

a. Claim 40 is Directed to a Main Stent and a Support Stent which are Configured Differently from Each Other

Claim 40 is directed to a covered stent that includes a main stent with a radially expandable body and a support stent that is plastically deformed. As set forth in Applicants'

Specification, the support stent "*may be partially plastically deformed, such at discrete points or along a region, or may be wholly plastically deformed.*" (Applicants' Specification, Paragraph 35, page 9, lines 10 to 11).

In contrast, the Love '723 reference discloses two methods of assembling its device. First, the inner helical support element **16** of the Love '723 reference is placed over a mandrel **50** (Column 8, Lines 17 to 18). A trimmed sheet of tissue **12** is then rolled over the mandrel **50**, and the outer helical support element **14** is placed over the tissue **12** by expanding the diameter of the helix and, after properly positioning over the tissue **12**, allowing the helix to contract onto the tubular form of the tissue (Column 8, Lines 18 to 24). Alternatively, in a second method of assembly, the outer helical support element **14** is applied by screwing the helices together or by wrapping the coils of the outer helical support element **14** over the tissue wrapped over the inner helical support element **16** and mandrel **50** (Column 8, 26 to 30). The mandrel **50** is then removed (Column 8, Line 24). In either regard, the prosthesis **10** of the Love '723 reference does not utilize plastic-deformation in forming its device and, therefore, the Love '723 reference can not anticipate nor suggest the present invention as claimed in claim **40**.

b. <u>The Sheath of the Love '723 Reference is Bonded to the Elements</u>

As pointed out above, not only does claim 40 include a combination of features, wherein no portions of the main stent is in contact with any part of the support stent with the pressing

force of both stents solely acting to hold the sheath in place, claim 40 also includes the feature of the sheath not being bonded to the support stent.

The Love '723 reference discloses bonding the sheath. In particular, "*the tissue will be overlapped by the requisite amount and will be held together by the tubular support frame.... In some cases, however, it may be further desirable to provide adhesives, such as fibrin glues, biological adhesives, synthetic glues (cyanoacrylates), or the like, to bond the overlapping layers.*" (Column 7, Lines 12 to 16). Thus, according to the Love '723 reference, it is clear that the sheet of tissue harvested from a patient or other animal source, "*will usually be treated with glutaraldehyde or other fixative or cross-linking agent, as also described previously.*" (Column 8, lines 8 to 11).

In sum, the Love '723 reference fails to include all of the features of the invention mentioned above and, as such, the Love '723 reference fails to anticipate the present invention as claimed in claim 40.

3. <u>Claim 48</u>

According to claim 48, the sheath is a polymeric material. In contrast, the Love '723 reference requires sheets harvested from non-polymeric material. Specifically, the Love '723

reference is directed "*to a method and apparatus for forming vascular prosthesis from host tissue sources.*" (Column 1, lines 7 to 10). According to the background of the Love '723 reference, because a variety of synthetic and non-autologous and smaller synthetic prostheses occlude at a relatively high rate, the Love '723 reference is directed to preparation of vascular prostheses from autologous pericardium (a natural tissue). (Column 1, lines 39 to 55). This is further confirmed in the Summary of the Invention, wherein it states that the "*vascular prostheses are formed in part from animal tissue, usually autologous tissue from the patient receiving the prostheses, which is supported on a separate support frame.*" (Column 2, Lines 58 to 61).

The requirement for the use of natural tissue in the Love '723 reference is substantiated in numerous other places in the specification as well. The following chart lists specific references discussing the material of the Love '723 device.

No.	Text Evidencing the Material of the Sheet	Map
1	*The vascular prostheses are formed in part from animal tissue, usually autologous tissue from the patient receiving the prostheses, which is supported on a separate support frame.*	Col. 2, Ll. 58-61
2	*When using autologous tissue, the grafts are biocompatible and non-immunogenic.*	Col. 3, Ll. 9-10
3	*The tissue sheet may be obtained from the host or from other human or animal (non-autologous) sources.*	Col. 3, Ll. 27-30
4	*The tissue employed in the vascular prosthesis will be obtained from a human or other animal source, usually but not necessarily being obtained from the patient or host into which the prosthesis is to be*	Col. 5, Ll. 8-11

	implanted.	
5	*While it is preferred that the tissue be obtained from the patient in which the vascular prosthesis is to be implanted (referred to as "autologous" tissue), it is also possible to obtain tissue from other human and animal sources. For example, tissue could be obtained from human cadavers, including frozen (cryo-preserved) cadaver tissue, treated with the cross-linking or other preserving agent, and then employed to make vascular prostheses according to the teachings herein.*	Col. 5, Ll. 44-52
6	*Referring now to FIGS. 5-8, a method for preparing the vascular prosthesis 10 of FIGS. 1-3 will be described. A sheet of tissue T is harvested from the patient or other animal source, as described previously.*	Col. 8, Ll. 6-9

Thus, it is clear that the Love '723 reference is geared toward a device requiring a sheet manufactured from a non-polymeric material. Claim 48 requires a "polymeric sheath". It is respectfully submitted that the Love '723 reference can not anticipate the present invention as claimed in claim 48.

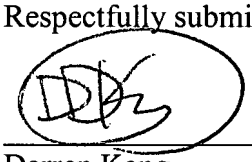
C. <u>Conclusion</u>

For the reasons set forth above, neither the Von Oepen et al. '264 reference nor the Love '723 reference disclose or suggest a main stent and a support stent with a layer therebetween as set forth in the claims. Thus, it is Applicants' position that claims 17 to 20, 22 to 24 and 39 to 55 are patentable.

For the record, claims 25-27 have not been canceled and are presently pending in the application. These claims were previously withdrawn in view of an election requirement. With an indication of allowance of claim 17, it is respectfully submitted that claims 25-27 should be re-entered into the application and also allowed.

Favorable action is earnestly solicited and a finding of patentability of claims 17 to 20, 22 to 24 and 39 to 55 is respectfully requested.

Respectfully submitted,



Darren Kang
Registration No. 51,859
Attorney for Appellant

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791
(973) 331-1700

X. Claims Appendix

17. A covered stent comprising

a main stent having a radially-expandable body,

at least one support stent having an axial length less than the axial length of said body, and

a sheath interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent, wherein said at least one support stent generates a relative pressing force with said main stent to hold said sheath in place, said sheath being not bonded to said at least one support stent with said pressing force solely acting to hold said sheath in place.

18. A covered stent as in claim 17, wherein said at least one support stent is plastically-deformed.

19. A covered stent as in claim 17, wherein said sheath is disposed radially outwardly of said main stent.

20. A covered stent as in claim 17, wherein said sheath is disposed radially inwardly of said main stent.

22. A covered stent as in claim 17, wherein said at least one support stent is disposed in proximity to an end of said body.

23. A covered stent as in claim 17, wherein said sheath is selected from the group consisting of a polymeric sleeve, a biomaterial sleeve, and a natural blood vessel.

24. A covered stent as in claim 17, wherein said sheath is treated with a drug selected from the group consisting of pharmaceutical agents, radioactive agents, bioactive agents, and combinations thereof.

39. A covered stent as in claim 17, wherein said sheath is not bonded to said main stent.

40. A covered stent comprising

a main stent having a radially-expandable body,

at least one support stent, and

a sheath interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent, wherein said at least one support stent is plastically-deformed and generates a relative pressing force with said main stent to hold said sheath in place, said sheath being not bonded to said at least one support stent with said pressing force solely acting to hold said sheath in place.

41. A covered stent as in claim 40, wherein said sheath is disposed radially outwardly of said main stent.

42. A covered stent as in claim 40, wherein said sheath is disposed radially inwardly of said main stent.

43. A covered stent as in claim 40, wherein said at least one support stent has an axial length which is less than the axial length of said body.

44. A covered stent as in claim 40, wherein said at least one support stent is disposed in proximity to an end of said body.

45. A covered stent as in claim 40, wherein said sheath is selected from the group consisting of a polymeric sleeve, a biomaterial sleeve, and a natural blood vessel.

46. A covered stent as in claim 40, wherein said sheath is treated with a drug selected from the group consisting of pharmaceutical agents, radioactive agents, bioactive agents, and combinations thereof.

47. A covered stent as in claim 40, wherein said sheath is not bonded to said main stent.

48. A covered stent comprising

a main stent having a radially-expandable body,

at least one support stent, and

a polymeric sheath interposed between said body and said at least one support stent with no portions of said main stent being in contact with said at least one support stent, wherein said at least one support stent generates a relative pressing force with said main stent to hold said sheath in place, said sheath being not bonded to said at least one support stent with said pressing force solely acting to hold said sheath in place.

49. A covered stent as in claim 48, wherein said at least one support stent is plastically-deformed.

50. A covered stent as in claim 48, wherein said sheath is disposed radially outwardly of said main stent.

51. A covered stent as in claim 48, wherein said sheath is disposed radially inwardly of said main stent.

52. A covered stent as in claim 48, wherein said at least one support stent has an axial length which is less than the axial length of said body.

53. A covered stent as in claim 48, wherein said at least one support stent is disposed in proximity to an end of said body.

54. A covered stent as in claim 48, wherein said sheath is treated with a drug selected from the group consisting of pharmaceutical agents, radioactive agents, bioactive agents, and combinations thereof.

55. A covered stent as in claim 48, wherein said sheath is not bonded to said main stent.

XI. Evidence Appendix

None.

XII. Related Proceedings Appendix

Appellants are not aware of any related proceedings.